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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/325,278	10/26/94	BJORCK	L 216764

EXAMINER

18N2/0106

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ART UNIT	PAPER NUMBER
1817	17

DATE MAILED: 01/06/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire _____ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☐ Claim(s) _____ is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☐ Claim(s) _____ is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Pate... ...ation, PTO-152

...E ACTION ON THE FOLLOWING PAGES--

Office Action Summary	Application No. 08/325,278	Applicant(s) Bjorck et al.
	Examiner Anthony C. Caputa	Group Art Unit 1817

☒ Responsive to communication(s) filed on *29 Sep 1997* .

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *3-5 and 11-13* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *3-5 and 11-13* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

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Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Applicants' amendment was received and entered as Paper No. 16. However, the amendment to page 5, line 3 was not entered since it is not clear where the phrase "SUMMARY OF THE INVENTION" is to be entered. Additionally, the amendment to page 5, line 26 and page 9, lines 15 and 16 was not entered since the phrase as set forth in applicants amendment were not present on the lines indicated by applicants. Furthermore, the amendment requesting moving the section to page 5, line 21 was not entered as requested. The Examiner requests applicants provide a substitute specification incorporating the amendments as set forth above.

Specification

2. The prior objection to the specification for being informal is withdrawn in view of applicants' amendment.

3. The prior objection for not complying with the sequence rules is withdrawn in view of applicants' amendment.

4. The prior objection to disclosure is withdrawn in view of applicants' amendment.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

6. The prior rejection of Claim 1 under 35 U.S.C. § 101 is withdrawn in view of applicants arguments.

Double Patenting

7. The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and © may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1, and 11-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 4,876,194 for the reason set forth in the last Office Action.

Applicants argue the rejection should be withdrawn in view that claims 1-14 of U.S. Patent No. 4,876,194 does not teach the sequence. Applicants are not sufficient to obviate the rejection. It is reasonable to conclude protein L as set forth in the issued patent is the same, or in the alternative an obvious or analogous variant of protein consisting of SEQ ID No. 1 as recited in the instant application since they have the same properties (useful as kit, useful as pharmaceutical composition, bind light chains of immunoglobulins, and from P. Magnus strain 312). Mere discovery that claimed composition possesses property not disclosed for prior art does not **alone** defeat prima facie case of obviousness and it is **not** necessary, in order to establish prima facie case, to show both structural similarity between claimed and prior art compound **and** suggestion in, or expectation from, prior art that claimed compound will have same or similar utility as one newly discovered by applicant. See In re Dillon, 16 USPQ2d 1897 (Fed. Cir. 1990).

For the reasons set forth above and in the last Office Action said rejection is maintained.

9. Claims 3-5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 4,876,194 in view of Guss et al. (WO 87/05361)(Art Cited by Applicants in the IDS) and Kastern et al. (1990) (Infection and Immunity 58(5):1217-22 5/90) (Art Cited by Applicants in the IDS) for the reason set forth in the last Office action.

Applicants argument is set forth above (see item 7). For the reasons set forth above and in the last Office Action said rejection is maintained.

Claim Rejections - 35 USC § 112

10. The prior rejection of claims 3, and 11-13 under 35 U.S.C. 112, second paragraph, for use of the phrase "domain which bind to heavy chains in immunoglobulin G" is withdrawn in view of applicants arguments.

11. The prior rejection of claims 11-13 under 35 U.S.C. 112, second paragraph, for failing to recite a second component in the composition is withdrawn in view of applicants amendment.

12. The prior rejection of claims 1, 3-5, and 11-13 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicants' arguments.

Claim Rejections - 35 USC § 102

13. Claims 1, and 11-13 are rejected under 35 U.S.C. 102(a) as being anticipated by Kastern et al. 1992 (J. Biol. Chemistry 267(18):12820-25 1992 (Art Cited by Applicants in the IDS)for the reason set forth in the last Office action.

Applicants argue the rejection should be withdrawn when a declaration is prepared stating the work of Kastern et al. Is that of the named inventors. Until applicants provide a proper declaration said rejection is maintained for the reasons set forth in the last Office Action.

14. Claims 1 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 255 497 (Art Cited by Applicants in the IDS).

Applicants argue the rejection should be withdrawn since even though EP 0 255 497 teaches subfragments the rejection should be withdrawn since it does not set forth the sequence of protein L. Applicants argument is not persuasive to overcome the rejection. Mere discovery that claimed composition possesses property not disclosed by prior art does not **alone** defeat prima facie case of anticipation. Since the claimed invention broadly encompasses subfragments of protein L and both the protein L as recited and set forth by EP 0 255 497 are capable of binding light chains of immunoglobulins the claimed invention is anticipated over the disclosure of EP 0 255 497. For the reasons set forth above and in the last Office Action said rejection is maintained.

In view of applicants arguments the Examiner concedes the protein L consisting of the amino acid sequence as recited in claim 1 and 11-13 is not anticipated over the disclosure of EP 0 255 497. However, since the claimed invention is not limited to a protein which has the amino acid sequence as recited the rejection of the claimed invention over EP 0 255 497 is maintained.

15. Claims 1 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 4,876,194 ('194) (Art Cited by Applicants in the IDS).

Applicants argue the rejection should be withdrawn since U.S. Patent No. 4,876,194 does not teach the sequence of protein L. Applicants are not sufficient to obviate the rejection. '194 does not characterize the protein as having the amino acid sequence as set forth in SEQ ID No.1. Nevertheless, since 1) the claimed invention broadly encompasses subfragments of protein L consisting (e.g. having the) of the amino acid sequence and 2) both the protein L as recited and

set forth by '194 are capable of binding light chains of immunoglobulins the claimed invention is anticipated over the disclosure of '194.

Since the Patent Office does not have the facilities for examining and comparing applicants' proteins with the proteins of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed proteins and the proteins of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

For the reasons set forth above and in the last Office Action said rejection is maintained.

Claim Rejections - 35 USC § 103

16. The prior rejection of claims 4-6 under 35 U.S.C. 103(a) as being unpatentable over EP 0 255 497 (Art Cited by Applicants in the IDS) and further in view of Kastern et al. 1990 (Infection and Immunity 58(5):1217-22 5/90) (Art Cited by Applicants in the IDS) and Guss et al. (WO 87/05361) (Art Cited by Applicants in the IDS) is withdrawn in view of applicants arguments of unexpected results (e.g. superior binding properties of the hybrid protein).

17. The prior rejection of claims 4-6 under 35 U.S.C. 103(a) as being unpatentable over Kastern et al. 1992 (J. Biol. Chemistry 267(18):12820-25 1992 (Art Cited by Applicants in the IDS)) and Guss et al. (WO 87/05361)(Art Cited by Applicants in the IDS) is withdrawn in view of applicants arguments of unexpected results.

18. The prior rejection of Claims 4-6 under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,876,194 ('194) (Art Cited by Applicants in the IDS) and Guss et al. (WO 87/05361) (Art Cited by Applicants in the IDS) is withdrawn in view of applicants arguments of unexpected results.

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Anthony C. Caputa, whose telephone number is (703)-308-3995. The examiner can be reached on Monday-Thursday from 8:30 AM-6:00 PM. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703)-308-0196.

Papers related to this application may be submitted to Art Unit 1817 by facsimile transmission. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The Fax number is (703)-308-4242

Anthony C. Caputa, Ph.D.
January 5, 1997

ANTHONY C. CAPUTA
PRIMARY EXAMINER
GROUP 1800